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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
BLUMEL, BENJAMIN P	
ART UNIT	**PAPER NUMBER**
1648	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/533,464	MAYERESSE ET AL.	
	Examiner	Art Unit	
	Benjamin P. Blumel	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) *16-19 and 25-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15 and 20-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 April 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/29/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of invention I in the reply filed on July 2, 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Furthermore, the required species elections were not made.

Claims 16-19 and 25-32 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on July 2, 2007.

Claims 1-15 and 20-24 are examined on the merits.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on April 29, 2005 was filed. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner. Foreign Patent documents WO 96/40077, WO 99/13906 and WO 98/00167 have not been considered since the proper country code has not been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-12, 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boutriau et al (US 2003/0180316 A1) and Troung-Le et al. (US 7,135,180 B2).

The claimed invention is drawn to a vaccine composition of an inactivated polio virus (IPV), a capsular saccharide from *Haemophilus influenzae* b (Hib) and/or *N. meningitides* A, C, Y or W, or a combination thereof, which are conjugated to either a carrier protein (the same type or different proteins) or a tetanus toxoid (TT) and a stabilizing agent. The composition has been dried either by freeze-dried process and the polysaccharide or oligosaccharide are adsorbed onto aluminium phosphate. The claimed invention is also drawn to a kit comprising one container with the IPV, Hib and *N. meningitides* saccharides, dried and another container with liquid acellular or whole cell DTP and Hepatitis B surface antigen (HBV-SAg).

Boutriau et al. teach a multi-valent vaccine composition comprising IPV of types 1, 2 and 3 (most preferably the Salk polio vaccine), which is the IPV utilized in the instant application, polysaccharides of Hib and *N. meningitides* A, C, Y and W, which can be conjugated to carrier

proteins. Or in the case of Hib saccharides, it can be conjugated to TT. Furthermore, Boutriau et al. teach the additional antigens from Diphtheria toxoid and whole cell Pertussis (DTPw) and Hepatitis B antigens can also be considered in the multi-valent vaccine. Boutriau et al. teach a kit comprising the various antigens, which can be placed into two separate vials. One vial could contain DTPw and Hepatitis B, and the other could contain Hib and *N. meningitidis* saccharides. Boutriau et al. also teach the use of aluminium phosphate as an adjuvant in order to complement the administered antigens by adsorption to them and the use of sucrose, a stabilizing agent, when lyophilizing a sample. However, Boutriau et al. do not teach the specific drying of IPV with a stabilizing agent and a bacterial saccharide.

Truong-Le, V. is drawn to methods of preserving viruses, bacteria, vaccines, nucleic acids, antibodies, etc. with stabilizing agents such as sucrose, mannitol or sorbitol. The stored compositions can be kept in a freeze-dried (i.e. lyophilized) state.

It would have been obvious to one of ordinary skill in the art to modify the compositions taught by Boutriau et al. in order to provide a dried vaccine of IPV and bacterial saccharides with a stabilizing agent present. One would have been motivated to do so, given the suggestion by Boutriau et al. that the compositions be modified in order to incorporate the various antigens of interest into a stable vaccine composition with sucrose, a stabilizing agent followed by lyophilization. There would have been a reasonable expectation of success, given the knowledge that several methods of freeze drying (lyophilization) vaccine compositions with various stabilizing agents increases the potential shelf life for said vaccine, as taught by Truong-Le, V. Thus the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 1-4, 11-13, 22 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kurikka et al. (Journal of Pediatrics, 1996) and Truong-Le, Vu (US 7,135,180 B2).

The claimed invention is drawn to a vaccine composition of an inactivated polio virus (IPV), a capsular saccharide from *Haemophilus influenzae* b (Hib), which is conjugated to either a carrier protein or a tetanus toxoid (TT) and a stabilizing agent. The composition has been dried either by freeze-dried process or as a foamed glass composition stored in a container with a water repellent interior.

Kurikka et al. focus on vaccination with multiple antigens of Hib, IPV, PRP-D, PRP-T and DTP. In particular, PRP-T contained lyophilized tetanus toxoid conjugated to *Haemophilus influenzae* b polysaccharide. Kurikka et al. also teach the increased immunogenecity to polysaccharides that are coupled to a carrier protein. These vaccines were kept in a glass vial (which inherently has water repellent surface). However, Kurikka et al. do not teach the lyophilization or stabilizing of the vaccines as a foamed glass composition of the combined antigens in a vaccine.

Truong-Le, V. is drawn to methods of preserving viruses, bacteria, vaccines, nucleic acids, antibodies, etc. with stabilizing agents such as sucrose, mannitol or sorbitol. The stored compositions can be kept in a freeze-dried (i.e. lyophilized) state or as a foamed glassy matrix.

It would have been obvious to one of ordinary skill in the art to modify the compositions taught by Kurikka et al. in order to freeze dry or to form a multi-valent vaccine as a foamed glass composition with a stabilizing agent. One would have been motivated to do so, given the suggestion by Kurikka et al. that a combined composition be utilized in a vaccine regime. There would have been a reasonable expectation of success, given the knowledge that combining

multiple antigens into a vaccine composition and stabilizing with various sugars before drying it into a freeze-dried or foamed glass composition, as taught by Troung-Le V. Thus the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear how a highly viscous liquid can be a dried composition since the viscosity implies it is in liquid form. Claim 15 is indefinite since it depends on claim 14.

Claim 23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear whether the claimed invention is drawn to a product or a method since claim 23 recites a vaccine but also contains a step from a method of vaccination.

Claim Objections

Claim 12 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 11. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim

to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Summary

No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin P. Blumel whose telephone number is 571-272-4960. The examiner can normally be reached on M-F, 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-1600. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Benjamin P Blumel/

Examiner
Art Unit 1648

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SUPERVISORY PATENT EXAMINER
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